



DEPARTMENT OF COMMERCE

Patent and Trademark Office

Patent Term Extension

ACTION: Notice of renewal of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension of an existing information collection: 0651-0020 (Patent Term Extension).

DATES: Written comments must be submitted on or before **[INSERT DATE 60 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments by any of the following methods:

- *Email:* InformationCollection@uspto.gov. Include “0651–0020 comment” in the subject line of the message.
- *Federal Rulemaking Portal:* <http://www.regulations.gov>.
- *Mail:* Marcie Lovett, Records and Information Governance Branch, Office of the Chief Administration Officer, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Raul Tamayo, Senior Legal Advisor, Office of Patent Legal Administration, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–7728; or by email to Raul.Tamayo@uspto.gov with “0651–0020 comment” in the subject line. Additional

information about this collection is also available at <http://www.reginfo.gov> under “Information Collection Review.”

SUPPLEMENTARY INFORMATION:

I. Abstract

The patent term restoration portion of the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417), which is codified at 35 U.S.C. § 156, permits the United States Patent and Trademark Office (USPTO) to extend the term of protection under a patent to compensate for delay during regulatory review and approval by the Food and Drug Administration (FDA) or Department of Agriculture. Only patents for drug products, medical devices, food additives, or color additives are potentially eligible for extension. The maximum length that a patent may be extended under 35 U.S.C. § 156 is five years. The USPTO administers 35 U.S.C. § 156 through 37 CFR 1.710-1.791.

This collection covers information gathered in patent term extension applications submitted under 35 U.S.C. § 156(d). Under this provision, an application for patent term extension must identify the approved product; the patent to be extended; and the claims included in the patent that cover the approved product, a method of using the approved product, or a method of manufacturing the approved product. 35 U.S.C. § 156(d) also requires the application for patent term extension to provide a brief description of the activities undertaken by the applicant during the regulatory review period with respect to the approved product and the significant dates of these activities.

This collection also covers information gathered in requests for interim extensions pursuant to 35 U.S.C. § 156(e). Under this provision an interim extension

may be granted if the term of an eligible patent for which an application for patent term extension has been submitted would expire before a certificate of extension is issued. Under 35 U.S.C. § 156(d)(5), an interim extension may be granted if the applicable regulatory review period that began for a product is reasonably expected to extend beyond the expiration of the patent term in effect. In addition, this collection covers requests for review of final eligibility decisions, and to withdraw an application requesting a patent term extension after it is submitted.

Separate from the extension provisions of 35 U.S.C. § 156, the USPTO may in some cases extend the term of an original patent under the provisions at 35 U.S.C. § 154 due to certain delays in the prosecution of the patent application, including delays caused by interference proceedings, secrecy orders, or appellate review by the Patent Trial and Appeal Board or a Federal court in which the patent is issued pursuant to a decision reversing an adverse determination of patentability. The USPTO administers 35 U.S.C. § 154 through 37 CFR 1.701-1.705. The patent term provisions of 35 U.S.C. § 154(b), as amended by Title IV, Subtitle D of the Intellectual Property and Communications Omnibus Reform Act of 1999, allow the applicant an opportunity to request reconsideration of the USPTO's patent term adjustment determination. This collection covers information gathered in such a request. In addition, this collection covers instances when the USPTO may reduce the amount of patent term adjustment granted if delays were caused by an applicant's failure to make a reasonable effort to respond within three months of the mailing date of a communication from the USPTO. Applicants may petition for reinstatement of a reduction in patent term adjustment with a

showing that, in spite of all due care, the applicant was unable to respond to a communication from the USPTO within the three-month period.

The information in this collection is used by the USPTO to consider whether an applicant is eligible for a patent term extension or reconsideration of a patent term adjustment and, if so, to determine the length of the patent term extension or adjustment.

II. Method of Collection

By mail, facsimile, hand delivery, or electronically to the USPTO.

III. Data

OMB Number: 0651–0020.

IC Instruments and Forms: There are no forms associated with this collection.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses or other for-profits; not-for-profit institutions.

Estimated Number of Respondents: 620 responses per year. The USPTO estimates that approximately 25% (155) of these responses will be from small entities.

Estimated Time per Response: The USPTO estimates that it will take the public from 1 to 25 hours, depending on the complexity of the situation, to gather the necessary information, prepare the appropriate documents, and submit the information to the USPTO.

Estimated Total Annual Respondent Burden Hours: 4,102 hours.

Estimated Total Annual Respondent (Hourly) Cost Burden: \$1,796,676.00. The USPTO expects that attorneys will complete these applications. The professional hourly rate for intellectual property attorneys is \$438. The attorney rates are found in the 2017 Report of the Economic Survey of the America Intellectual Property Law Association (AIPLA). Using this hourly rate, the USPTO estimates that the total respondent cost burden for this collection is \$1,796,676.00 per year.

#	Item	Estimated Time for Response (hours) (a)	Estimated Annual Responses (b)	Estimated Annual Burden Hours (a) x (b) = (c)	Rate (\$/hr) (d)	Total Hourly Cost Burden (\$/hr) (c) x (d) = (e)
1	Application to Extend Patent Term Under 35 U.S.C. § 156	25	100	2,500	\$438.00	\$1,095,000.00
2	Request for Interim Extension Under 35 U.S.C. § 156(e)(2)	1	10	10	\$438.00	\$4,380.00
3	Petition to Review Final Eligibility Decision Under 37 CFR 1.750	25	4	100	\$438.00	\$43,800.00
4	Initial Application for Interim Extension Under 37 CFR 1.790	20	2	40	\$438.00	\$17,520.00
5	Subsequent Application for Interim Extension Under 37 CFR 1.790	1	1	1	\$438.00	\$438.00
6	Response to Requirement to Elect	1	35	35	\$438.00	\$15,330.00
7	Response to Request to Identify Holder of Regulatory Approval	2	1	2	\$438.00	\$876.00
8	Declaration to Withdraw an Application to Extend Patent Term	2	1	2	\$438.00	\$876.00
9	Petition for Reconsideration of Patent Term Adjustment Determination	3	450	1,350	\$438.00	\$591,300.00
10	Petition for Reinstatement of Reduced Patent Term Adjustment	4	15	60	\$438.00	\$26,280.00
11	Petition to Accord a Filing Date to an Application Under 37 CFR 1.740 for Extension of a Patent Term	2	1	2	\$438.00	\$876.00
	Total	----- -	620	4,102	-----	\$1,796,676.00

Estimated Total Annual (Non-hour) Respondent Cost Burden: \$209,488. There are no capital startup, maintenance, or operating fees associated with this collection. There are, however, annual (non-hour) costs in the form of postage costs and fees.

Filing Fees

There are filing fees associated with this collection. The items with filing fees are listed in the table below.

#	Item	Estimated Annual Responses (a)	Filing fee (\$) (b)	Total Non-hour Cost Burden (\$) (a) x (b) = (c)
1	Filing an application for patent term adjustment	450	\$200	\$90,000.00
2	Request for reinstatement of term reduced	15	\$400	\$6,000.00
3	Extension of term of patent	100	\$1,120	\$112,000.00
4	Initial application for interim extension (see 37 CFR 1.790)	2	\$420	\$840.00
5	Subsequent application for interim extension (see 37 CFR 1.790)	1	\$220	\$220.00
Total	-----	-----	\$2,360.00	\$209,060.00

Postage Costs:

Customers may incur postage costs when submitting some of the items covered by this collection to the USPTO by mail. The applications to extend patent term under 35 U.S.C. § 156 and the initial applications for interim extension under 37 CFR 1.790 cannot be filed electronically. The USPTO expects that 50 percent of these responses will be submitted by mail, resulting in 51 mailed submissions. (The reminder of the submission, in this category will be hand carried to USPTO.) The USPTO expects that

approximately 99 percent of the remaining responses in this collection will be submitted electronically. Of the remaining 1 percent, the vast majority will be submitted by mail, resulting in 5 additional mailed submissions. Overall for this collection, 56 mailed submissions are expected per year. The average USPS Priority Mail postage cost for a legal flat rate envelope is estimated to be \$7.65. Therefore, the USPTO estimates that the postage costs for the mailed submissions in this collection will total \$428.

Therefore, the USPTO estimates that the total annual (non-hour) cost burden for this collection, in the form of postage costs and fees is \$209,488 per year.

IV. Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

USPTO invites public comments on:

- (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information, including the validity of the methodology and assumptions used;
- (c) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (d) Ways to minimize the burden of the collection of information on respondents, e.g., including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Marcie Lovett,

Records and Information Governance Branch,

Office of the Chief Administrative Officer, USPTO.

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